

FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

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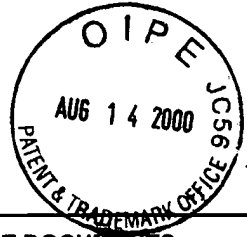
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09/023,401

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APPLICANT

Gary S. Jacob

FILING DATE

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## U.S. PATENT DOCUMENTS

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	27	3,590,028	6/1971	Arcamone	260	210	TECH CENTER 1600/2900
	28	4,042,448	3/1977	Smith et al.	260	591	
	29	4,065,562	12/1977	Ohata et al.	424	267	
	30	4,182,767	1/1980	Murai et al.	424	267	
	31	4,260,622	4/1981	Junge et al.	424	267	
	32	4,327,725	5/1982	Cortese et al.	128	260	
	33	4,524,060	6/1985	Mughal et al.	424	19	
	34	4,533,668	8/1985	Matsumura et al.	514	321	
	35	4,611,058	9/1986	Koebernick	546	242	
	36	4,612,008	9/1986	Wong et al.	604	892	
	37	4,765,989	8/1988	Wong et al.	424	473	
	38	4,783,337	11/1988	Wong et al.	424	468	
	39	4,806,650	2/1989	Schröder et al.	546	242	
B	40	4,849,430	7/1989	Fleet et al.	514	315	
	41	4,880,830	11/1989	Rhodes	424	470	
	42	4,957,926	9/1990	Jacob et al.	514	315	
P	43	5,003,072	3/1991	Partis et al.	546	243	
	44	5,011,829	4/1991	Hirsch et al.	514	50	
	45	5,030,638	7/1991	Partis et al.	514	315	
	46	5,041,441	8/1991	Radin et al.	514	237.8	
	47	5,068,112	11/1991	Samejima et al.	424	495	
	48	5,190,765	3/1993	Jao et al.	424	473	
7	49	5,144,037	9/1992	Partis et al.	546	116	

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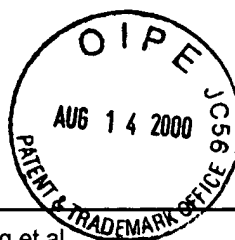
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<del>50</del>	<del>5,151,519</del>	<del>9/1992</del>	<del>Behling et al.</del>	<del>546</del>	<del>219</del>	
<del>51</del>	<del>5,281,724</del>	<del>1/1994</del>	<del>Behling et al.</del>	<del>549</del>	<del>334</del>	
<del>52</del>	<del>5,310,745</del>	<del>5/1994</del>	<del>Partis et al.</del>	<del>514</del>	<del>315</del>	
<del>53</del>	<del>5,331,096</del>	<del>7/1994</del>	<del>Koszyk et al.</del>	<del>546</del>	<del>115</del>	
<del>54</del>	<del>5,411,970</del>	<del>5/1995</del>	<del>Partis et al.</del>	<del>514</del>	<del>315</del>	
<del>55</del>	<del>5,451,679</del>	<del>9/1995</del>	<del>Barta et al.</del>	<del>546</del>	<del>219</del>	
<del>56</del>	<del>5,472,969</del>	<del>12/1995</del>	<del>Platt et al.</del>	<del>514</del>	<del>315</del>	
<del>57</del>	<del>5,491,135</del>	<del>2/1996</del>	<del>Blough</del>	<del>514</del>	<del>115</del>	
<del>58</del>	<del>5,525,616</del>	<del>6/1996</del>	<del>Platt et al.</del>	<del>514</del>	<del>315</del>	
<del>59</del>	<del>5,536,732</del>	<del>7/1996</del>	<del>Lesur et al.</del>	<del>514</del>	<del>317</del>	
<del>60</del>	<del>5,595,981</del>	<del>1/1997</del>	<del>Barta et al.</del>	<del>514</del>	<del>63</del>	
<del>61</del>	<del>5,612,480</del>	<del>3/1997</del>	<del>Barta et al.</del>	<del>544</del>	<del>180</del>	
<del>62</del>	<del>5,663,342</del>	<del>9/1997</del>	<del>Barta et al.</del>	<del>546</del>	<del>6</del>	


## FOREIGN PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
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<del>63</del>		<del>2,020,278</del>	<del>3/1979</del>	<del>U.K.</del>	<del>C07D</del>	<del>211/40</del>		
<del>64</del>		<del>0 324 328</del>	<del>7/1989</del>	<del>EPO</del>	<del>A61K</del>	<del>31/445</del>		
<del>65</del>		<del>0 350 012</del>	<del>1/1990</del>	<del>EPO</del>	<del>A61K</del>	<del>31/445</del>		
<del>66</del>		<del>0 367 748</del>	<del>5/1990</del>	<del>EPO</del>	<del>C07D</del>	<del>211/46</del>		
<del>67</del>		<del>0 449 026</del>	<del>10/1991</del>	<del>EPO</del>	<del>C07D</del>	<del>491/04</del>		
<del>68</del>		<del>0 494 850</del>	<del>7/1992</del>	<del>EPO</del>	<del>C07D</del>	<del>211/46</del>		
<del>69</del>		<del>0 566 556</del>	<del>10/1993</del>	<del>EPO</del>	<del>C07D</del>	<del>211/40</del>		
<del>70</del>		<del>WO87/03903</del>	<del>7/1987</del>	<del>PCT</del>	<del>C12N</del>	<del>05/00</del>		
<del>71</del>		<del>WO95/22975</del>	<del>8/1995</del>	<del>PCT</del>	<del>A61K</del>	<del>31/445</del>		
<del>72</del>		<del>WO96/40110</del>	<del>12/1996</del>	<del>PCT</del>	<del>A61K</del>	<del>31/35</del>		

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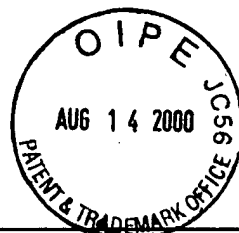
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<b>LIST OF PRIOR ART CITED BY APPLICANT</b> (Us sev ral sh ts if nec ssary)											
								<b>APPLICANT</b> Gary S. Jacob			
								<b>FILING DATE</b> 2-12-98		<b>GROUP</b> 1614	
73	WQ97/00884	1/1997	PCT	C07H	17/02		No				
74	WQ98/35685	8/1998	PCT	A61K	31/70						
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>											
75	Dalton, et al., "A Phase II Randomized Study of Oral Verapamil as a Chemosensitizer to Reverse Drug Resistance in Patients with Refractory Myeloma," February 1, 1995, Cancer, Vol. 75, No. 3, pp. 815-820										
76	Jacob et al., "Aminosugar Attenuation of HIV Infection," 1992, Natural Products as Antiviral Agents, pp. 137-152										
77	Karpas, et al., "Aminosugar Derivatives as Potential Anti-Human Immunodeficiency Virus Agents," December, 1988, Proc. Natl. Acad. Sci., Vol. 85, pp. 9229-9233										
78	Welsh, et al., "Accumulation of Fatty Alcohol in MCF-7 Breast Cancer Cells," November 15, 1994, Archives of Biochemistry and Biophysics, Vol. 315, No. 1, pp. 41-47										
79	Lavie, et al., "Agents that Reverse Multidrug Resistance, Tamoxifen, Verapamil, and Cyclosporin A, Block Glycosphingolipid Metabolism by Inhibiting Ceramide Glycosylation in Human Cancer Cells," August 20, 1996, The Journal of Biological Chemistry, Vol. 272, No. 3, pp. 1682-1687										
80	Lavie, et al., "Accumulation of Glucosylceramides in Multidrug-Resistant Cancer Cells," August 9, 1996, The Journal of Biological Chemistry, Vo. 271, No. 32, pp. 19530-19536										
81	Inokuchi, et al., "Antitumor Activity Via Inhibition of Glycosphingolipid Biosynthesis," September 3, 1987, Cancer Letters, Vol. 38, pp. 23-30										
82	Holleran, et al., "Characterization of Cellular Lipids in Doxorubicin-Sensitive and -Resistant P388 Mouse Leukemia Cells," 1986, Cancer Chemother Pharmacol, 17:11-15										
83	Fisher, et al., "Clinical Studies with Modulators of Multidrug Resistance," April 1995, Drug Resistance in Clinical Oncology and Hematology, Vol. 9, No. 2, pp. 363-382										
84	Raderer, et al., "Clinical Trials of Agents that Reverse Multidrug Resistance," December 15, 1993, Cancer, Vol. 72, No. 12, pp. 3553-3563										
85	Tan, et al., "Chemical Modification of the Glucosidase Inhibitor 1-Deoxynojirimycin," August 5, 1991, The Journal of Biological Chemistry, Vo. 266, No. 22, pp. 14504-14510										
86	Wang, et al., "Chemo-enzymatic Synthesis of Five-membered Azasugars as Inhibitors of Fucosidase and Fucosyltransferase: An Issue Regarding The Stereochemistry Discrimination at Transition States," 1993, Tetrahedron Letters, Vol. 34, No. 3, pp. 403-406										
87	Jezowska-Bojczuk, et al., "Copper(II) Interactions with an Experimental Antiviral Agent, 1-Deoxynojirimycin, and Oxygen Activation by Resulting Complexes," 1996, Journal of Inorganic Biochemistry, Vol. 64, pp. 231-246										
88	Ramu, et al., "Differences in Lipid Composition of Doxorubicin-Sensitive and -Resistant P388 Cells," April 1984, Cancer Treatment Reports, Vol. 68, No. 4, pp. 637-641										

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	89	Beketic-Oreskovic, et al., "Decreased Mutation Rate for Cellular Resistance to Doxorubicin and Suppression of mdr1 Gene Activation by the Cyclosporin PSC 833," November 1, 1995, Journal of the National Cancer Institute, Vol. 87, No. 21, pp. 1593-1602			
	90	Volm, et al., "Expression of Resistance Factors (P-Glycoprotein, Glutathione S-Transferase- $\pi$ , and Topoisomerase II) and Their Interrelationship to Proto-Oncogene Products in Renal Cell Carcinomas," June 15, 1993, Cancer, Vol. 71, No. 12, pp. 3981-3987			
	91	Lu, et al., "Evidence That N-Linked Glycosylation is Necessary for Hepatitis B Virus Secretion," November 10, 1995, Virology, Vol. 213, No. 2, pp. 660-665			
	92	Legler, et al., "Glycosylceramidase from Calf Spleen: Characterization of its Active Site with 4-n-Alkylumbelliferyl $\beta$ -glucoside and N-alkyl Derivatives of 1-Deoxynojirimycin," December 1985, Biochem Hoppe-Seyler, Vol. 366, pp. 1113-1122			
	93	Hardman, et al., "Goodman & Gilman's The Pharmacological Basis of Therapeutics," 1996, McGraw-Hill, Ninth Edition, Chapter 32: Drugs Used for the Treatment of Myocardial Ischemia," Verepamil, pp. 767-774, 780-781, 799-801, and 829			
	94	Mehta, et al., "Hepatitis B Virus (HBV) Envelope Glycoproteins Vary Drastically in Their Sensitivity to Glycan Processing: Evidence that Alteration of a Single N-Linked Glycosylation Site Can Regulate HBV Secretion," March 1997, Proc. Natl. Acad. Sci., Vol. 94, pp. 1822-1827			
	95	Hollinger, "Hepatitis B Virus," Field Virology, Third Edition, Chapter 86, pp. 2739-2807			
	96	Fleet, et al., "Inhibition of HIV Replication by Amino-Sugar Derivatives," September 1988, Federation of European Biochemical Societies, Vol. 237, No. 1,2, pp. 128-132			
	97	Newbrun, et al., "Inhibition by Acarbose, Nojirimycin and 1-Deoxynojirimycin of Glucosyltransferase Produced by Oral Streptococci," 1983, Archs Oral Biol., Vol. 28, No. 6, pp. 531-536			
	98	Saunier, et al., "Inhibition of N-Linked Complex Oligosaccharide Formation by 1-Deoxynojirimycin, An Inhibitor of Processing Glucosidases," December 10, 1982, The Journal of Biological Chemistry, Vol. 257, No. 23, pp. 14155-14161			
	99	Abe, et al., "Induction of Glycosylceramide Synthase by Synthase Inhibitors and Ceramide," 1996, Biochimica et Biophysica Acta, Vol. 1299, pp. 333-341			
	100	Abe, et al., "Improved Inhibitors of Glucosylceramide Synthase," 1992, J. Biochem., Vol. 111, pp. 191-196			
	101	Elbein, "Inhibitors of the Biosynthesis and Processing of N-Linked Oligosaccharide Chains," 1987, Ann. Rev. Biochem., 56:497-534			
	102	Radin, et al., "Inhibitors of Cerebroside Metabolism," 1981, Methods in Enzymology, Vol. 72, pp. 673-684			
	103	Prencipe, et al., "In Vitro Accumulation of Glucocerebroside in Neuroblastoma Cells: A Model for Study of Gaucher Disease Pathobiology," 1996, Journal of Neuroscience Research, 43:365-371			



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	104	Bradley, et al., "Mechanism of Multidrug Resistance," 1988, Biochimica et Biophysica Acta, Vol. 948, pp. 87-128			
	105	Mulder, et al., "Multidrug Resistance-Modifying Components in Human Plasma with Potential Clinical Significance," January 1996, Journal of Experimental Therapeutics & Oncology, Vol. 1, No. 1, pp. 13-22			
	106	Ardalan, et al., "Mechanism of Action of a New Antitumor Agent, Carbetimer," November, 1986, Cancer Research, Vol. 46, pp. 5473-5476			
	107	Platt, et al., "Modulation of Cell Surface Transferrin Receptor by the Imino Sugar N-butyldeoxynojirimycin," 1992, Eur. J. Biochem., Vol. 208, pp 187-193			
	108	Kawakami, et al., "Monoclonal Antibodies with Affinity to Self-Complementary Left-Handed DNA Containing Cyclonucleosides with High Anti Conformation," 1994, Nucleosides & Nucleotides, Vol. 13(1-3), pp. 421-427			
	109	Dicato, et al., "Multidrug Resistance: Molecular and Clinical Aspects," 1997, Cytokines, Cellular & Molecular Therapy, Vol. 3, No. 2, pp. 91-100			
	110	Bolhuis, et al., "Mechanisms of Multidrug Transporters," 1997, FEMS Microbiology Reviews, Vol. 21, pp. 55-84			
	111	Carbohydrate Chemistry, "Chapter 20: Nucleosides," undated, pp. 242-276			
	112	Platt, et al., "N-Butyldeoxynojirimycin Is a Novel Inhibitor of Glycolipid Biosynthesis," March 18, 1994, The Journal of Biological Chemistry, Vol. 269, No. 11, pp. 8362-8365			
	113	Platt, et al., "N-Butyldeoxygalactonojirimycin Inhibits Glycolipid Biosynthesis but Does Not Affect N-Linked Oligosaccharide Processing," October 28, 1994, The Journal of Biological Chemistry, Vol. 269, No. 43, pp. 27108-27114			
	114	Platt, et al., "New Approach for the Treatment of Gauchers Disease," March 1996, Gauchers Association Newsletter, one page			
	115	Wilson, et al., "Nitrogen Glycosylation Reactions Involving Pyrimidine and Purine Nucleoside Bases with Furanoside Sugars," December 1995, Synthesis, Department of Chemistry, Emory University, pp. 1465-1479			
	116	Kers, et al., "Nucleoside Phosphonates: Development of Synthetic Methods and Reagents," 1996, Nucleosides & Nucleotides, 15(1-3), pp. 361-378			
	117	Tsuruo, et al., "Overcoming of Vincristine Resistance in P388 Leukemias In Vivo and In Vitro Enhanced Cytotoxicity of Vincristine and Vinblastine by Verapamil," May 1981, Cancer Research, Vol. 41, pp. 1967-1972			
	118	Wright, et al., "Phospholipid and Ether Linked Phospholipid Content Alter with Cellular Resistance to Vinblastine," December 17, 1985, Biochemical and Biophysical Research Communications, Vol. 133, No. 2, pp. 539-545			
	119	Bradley, et al., "P-glycoprotein, Multidrug-Resistance and Tumor Progression," 1994, Cancer and Metastasis Reviews, Vol. 13, pp. 223-233			
	120	May, et al., "Plasma Membrane Lipid Composition of Vinblastine Sensitive and Resistant Human Leukaemic Lymphoblasts," 1988, Int. J. Cancer, Vol. 42, pp. 728-733			

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	121	<del>Platt, et al., "Prevention of Lysosomal Storage in Tay-Sachs Mice Treated with N-Butyldeoxynojirimycin," April 18, 1997, Science, Vol. 276, pp. 428-431</del>			
	122	<del>Wishart, et al., "Quinidine as a Resistance Modulator of Epirubicin in Advanced Breast Cancer: Mature Results of a Placebo-Controlled Randomized Trial," September 1994, Journal of Clinical Oncology, Vol. 12, No. 9, pp. 1771-1777</del>			
	123	<del>Chabner, et al., "Reversal of Multidrug Resistance," January 1991, Journal of Clinical Oncology, Vol. 9, No. 1, pp. 4-6</del>			
	124	<del>Hui, et al., "Reduced p21<sup>WAF1/CIP1</sup> Expression and p53 Mutation in Hepatocellular Carcinomas," March 1997, Hepatology, Vol. 25, No. 3, pp. 575-579</del>			
	125	<del>Radin, "Rationales for Cancer Chemotherapy with PDMP, a Specific Inhibitor of Glucosylceramide Synthase," 1994, Molecular and Chemical Neuropathology, Vol. 21, pp. 111-127</del>			
	126	<del>Arends, "Recueil des Travaux Chimiques des Pays-Bas," Journal of the Royal Netherlands Chemical Society, February 1994, Recl. Trav. Chim. Pays-Bas 113, 63-114, contents page only</del>			
	127	<del>Shukla, et al., "Rapid Kidney Changes Resulting from Glycosphingolipid Depletion by Treatment with a Glucosyltransferase Inhibitor," 1991, Biochimica et Biophysica Acta., Vol. 1083, pp. 101-108</del>			
	128	<del>Block, et al., "Secretion of Human Hepatitis B Virus is Inhibited by the Imino Sugar N-butyldeoxynojirimycin," March 1994, Proc. Natl. Acad. Sci., Vol. 91, pp. 2235-2239</del>			
	129	<del>Inokuchi, et al., "Stimulation of Glycosphingolipid Biosynthesis by L-Threo-1-Phenyl-2-Decanoylamino-1-Propanal and Its Homologs in B16 Melanoma Cells," 1995, J. Biochem., Vol. 117, No. 4, pp. 766-773</del>			
	130	<del>Abe, et al., "Structural and Stereochemical Studies of Potent Inhibitors of Glucosylceramide Synthase and Tumor Cell Growth," 1995, Journal of Lipid Research, Vol. 36, pp. 611-621</del>			
	131	<del>Ogawa, et al., "Synthesis of Potent <math>\beta</math>-D-Glucocerebrosidase Inhibitors: N-Alkyl-<math>\beta</math>-Valienamines," 1996, Bioorganic &amp; Medicinal Chemistry Letters, Vol. 6, No. 8, pp. 929-932</del>			
	132	<del>Vorbrüggen, et al., "Some Recent Trends and Progress in Nucleoside Synthesis," 1996, Acta Biochimica Polonica, Vol. 43, No. 1, pp. 25-36</del>			
	133	<del>Sobrero, et al., "Sequential Dichloromethotrexate (DCM) and 5-Fluorouracil (FU): A Synergistic Combination Potentially Valuable for Hepatic Artery Infusion Therapy," March 1983, ASCO Abstracts, Clinical Pharmacology, Vol. 2, Article C-102, p. 26</del>			
	134	<del>Wadkins, et al., "The Role of Drug-Lipid Interactions in the Biological Activity of Modulators of Multi-Drug Resistance," 1993, Biochimica et Biophysica Acta, Vol. 1153, pp. 225-236</del>			
	135	<del>Doige, et al., "The Effects of Lipids and Detergents on ATPase-Active P-Glycoprotein," 1993, Biochimica et Biophysica Acta, Vol. 1146, pp. 65-72</del>			
	136	<del>Ries, et al., "Treatment of Advanced and Refractory Breast Cancer with Doxorubicin, Vincristine and Continuous Infusion of Verapamil. A Phase I-II Clinical Trial," 1991, Med. Oncol. &amp; Tumor Pharmacother, Vol. 8, No. 1, pp. 39-43</del>			

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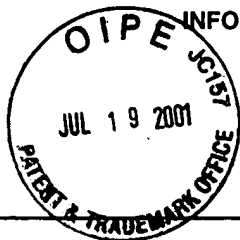
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	137	Radin, et al., "Treatment of Gaucher Disease with an Enzyme Inhibitor," 1996, Glycoconjugate Journal, Vol. 13, pp. 153-157			
	138	Fischl, et al., "The Safety and Efficacy of Combination N-Butyl-Deoxynojirimycin (SC-48334) and Zidovudine in Patients with HIV-1 Infection and 20-500 CD4 Cells/mm <sup>3</sup> ," 1994, Journal of Acquired Immune Deficiency Syndromes, Vol. 7, pp. 139-147			
	139	Block, et al., "The Secretion of Human Hepatitis B Virus is Inhibited by the Imino Sugar, N-Butyl-Deoxynojirimycin," undated, Jefferson Cancer Institute, et al., No. 81, one page			
✓	140	Mutchnick, et al., "Thymosin Treatment of Chronic Hepatitis B: A Placebo-controlled Pilot Trial," 1991, Hepatology, Vol. 14, No. 3, pp. 409-415			
	141	Simon, et al., "Treatment of Chronic Hepatitis C with Interferon Alfa-n3: A Multicenter, Randomized, Open-Label Trial," February 1997, Hepatology, Vol. 25, No. 2, pp. 445-448			
	142	Cabot, et al., "Tamoxifen Retards Glycosphingolipid Metabolism in Human Cancer Cells," 1996, FEBS Letters (17548), Vol. 394, pp. 129-131			
	143	Lindsay, et al., "Thymosin $\alpha_1$ Treatment of Chronic Hepatitis B: A Multicenter, Randomized, Placebo-Controlled Double Blind Study," April 1995, AASLD, A1127, one page			
	144	Mutchnick, et al., "Thymosin Treatment of Chronic Active Hepatitis B (CAHB): A Preliminary Report on a Controlled, Double Blind Study," 1988, Hepatology, Vol. 8, No. 5, Article 208, p. 1270			
✓	145	Dwek, Raymond, "Glycobiology: Toward Understanding the Function of Sugars," Chem. Rev. 1996, 96, pp. 683-720			
Δ	146	Platt, Frances M., et al., "Inhibitors of Glycosphingolipid Biosynthesis," Trends in Glycoscience and Glycotechnology, Vol. 7, No. 38, November 1995, pp. 495-511			



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*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
<i>b</i>	147	4,269,857	5/1981	Tokuda et al.	424	325	
<i>b</i>	148	5,221,746	6/1993	Partis et al.	546	220	
	<del>149</del>	<del>5,264,356</del>	<del>11/1993</del>	<del>Rohrschneider</del>	435	236	
	<del>150</del>	<del>5,622,972</del>	<del>4/1997</del>	<del>Bryant et al.</del>	514	315	
	<del>151</del>	<del>5,703,058</del>	<del>12/1997</del>	<del>Schinazi et al.</del>	514	45	
	<del>152</del>	<del>6,093,702</del>	<del>7/2000</del>	<del>Malley et al.</del>	514	45	

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							YES	NO
	<del>153</del>	<del>2,700,267</del>	<del>1/1993</del>	<del>FR</del>	A61K	9/107		
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	<del>155</del>	<del>0,477,160</del>	<del>9/1991</del>	<del>ERO</del>	C12P	17/04		
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	<del>157</del>	<del>0,729,747</del>	<del>2/1996</del>	<del>EPO</del>	A61K	7/48		
	<del>158</del>	<del>WO91/17,145</del>	<del>11/1991</del>	<del>PCT</del>	C07D	211/46		
	<del>159</del>	<del>WO94/04546</del>	<del>3/1994</del>	<del>PCT</del>	C07H	17/02		Abstract
	<del>160</del>	<del>WO95/06061</del>	<del>3/1995</del>	<del>PCT</del>	C07K	5/03		
	<del>161</del>	<del>WO99/29321</del>	<del>6/1999</del>	<del>PCT</del>	A61K	31/445		
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<del>163</del>	<del>Acosta et al., "Agents for Treating Human Immunodeficiency Virus Infection," Am. J. Hosp. Pharm., Vol. 51, September 15, 1994, pp. 2251-2287</del>
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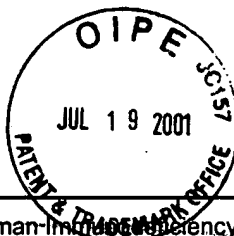
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